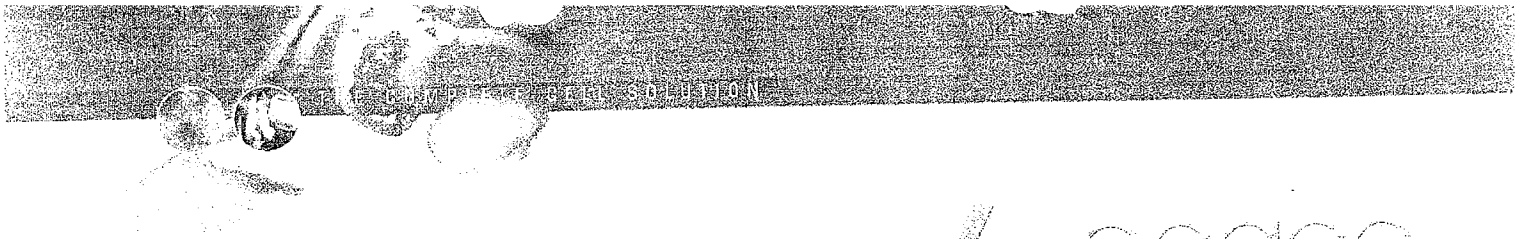

Health Protection Agency, Porton Down and European Collection of Cell Cultures

This document certifies that

Virus RAdEs

Deposit Reference 04121701

has been accepted as a patent deposit, in accordance with The Budapest Treaty of 1977, with the European Collection of Cell Cultures on 17 December 2004

. . . . . .

Dr D H Lewis
General Manager
ECACC

European Collection of Cell Cultures, Health Protection Agency, Centre For Emergency Preparedness and Response, Porton Down, Salisbury, Wiltshire SP4 0JG, UK.
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: ecacc@hpa.org.uk Web Site: ecacc.org.uk

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
DR S VRATI
NATIONAL INSTITUTE OF IMMUNOLOGY
VIROLOGY LABORATORY

NEW DELHI
110 067
INDIA

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR:
RAdEs

Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
04121701

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

[X] A scientific description

[ ] A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above, which was received by it on 17 December 2004 (date of the original deposit)[1]

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)

IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
HPA
Porton Down
Salisbury SP4 OJG

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):

Date: 27/1/05

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

1991

Form BP/4 (sole page)

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

DR S VRATI
NATIONAL INSTITUTE OF IMMUNOLOGY
VIROLOGY LABORATORY

NEW DELHI
110 067
INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY OF STATEMENT IS ISSUED

VIABILITY STATEMENT
Issued pursant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: DR S VRATI NATIONAL INSTITUTE OF IMMUNOLOGY VIROLOGY LABORATORY Address: NEW DELHI 110 067 INDIA	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 04121701 Date of the deposit or of the transfer: 17 December 2004

III. VIABILITY STATEMENT

The viability of the microorganism identified under II above was tested on [1] 17 December 2004 [2]. On that date, the said microorganism was

[X] [3] viable

[ ] [3] no longer viable

1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).

2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED [1]

The Virus Passage Deposit BADEs Accession Number 04121701 was tested according to the Depositor's protocol and shown to be infectious and viable.

II. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr D H Lewis
ECACC HPA

Address: Porton Down
Salisbury
Wiltshire
SP4 0JG

Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):

Date: 07/11/05

[1] Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

Patent Deposit Accession Form
Virus

DEPOSITOR INFORMATION

Name of Depositor/Company/Institute NATIONAL INSTITUTE OF IMMUNOLOGY

(NB this will be the name that appears on certification)

Contact Name DR. SUDHANSHU VRATI

Depositor Address NATIONAL INSTITUTE OF IMMUNOLOGY, NEW DELHI-110067

Tel No +91-11-26703696 Fax No +91-2-26162125 Email vrati@nii.res.in

BIOHAZARD STATEMENT MUST BE ENCLOSED

The deposit is made in accordance with the terms of the Budapest Treaty 1977. I agree to abide by the conditions and regulations regarding the deposit of cell lines to the ECACC.

Signature [signature] Date 16-JUNE-2004

Address to which invoice should be sent (if different from above)

DIRECTOR
NATIONAL INSTITUTEE OF IMMUNOLOGY
NEW DELHI - 110067

VIRUS INFORMATION

Name in full Recombinant human adenovirus

Abbreviated Name RAdES Identification on Ampoules RAdES

Strain Serological Type

Normal Host

Virus Titre Deposited

VIRUS PROPAGATION

Host cells (first choice) Human embryonic kidney 293cells

Alternative Host Cells None

Details of Host Cell Growth (media, temperature, seeding density, growth factors etc) Grown in ~~with~~ monolayers of HEK 293 cells cultured in DMEM+10% FCS.

Details of Virus Growth (eg confluency of host cells, co-cultivation, moi, effects, time taken) At moi 0·1 it takes ~36 hrs for CPE to appear - cells are then harvested & virus prepared.

VIRUS STORAGE

Material stored (eg supernatant, infected cell extract, viable infected cells etc)

Temperature and conditions Infected cell extract, to be stored at -70°C

VIRUS ASSAY

Method (enclose if necessary) Plaque assay on 293 cells.

LITERATURE REFERENCES (if any)

—

ANY OTHER RELEVANT INFORMATION —

Please Note: ECACC must receive full information regarding delivery at least 48 hours before despatch.

A Biohazard Risk Assessment must be completed in order for your samples to be accepted. ECACC is required to assess the GMO status of all deposits PRIOR to receipt. Therefore, we will contact all depositors to advise them when we can receive samples.

CAMR
Today's Research Tomorrow's Health

European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 E-mail: ecacc@camr.org.uk Web site: ecacc.org.uk

2. Does the GM agent contain/produce a biologically active substance that could potentially cause harm to humans (eg toxin, cytokine, hormone, allergen, oncogene)

Yes ☐ No ☑

3. What is the likelihood that the genetic modification can confer pathogenic traits in the host organism?

Negligible	Possible	Probably or Demonstrated
✓		

If "possible", "probably" or "demonstrated" please provide additional details:

.....

4. What is the potential for sequences within the GM being transferred to another related microorganism?

Negligible	Low	Medium	High
✓			

If "medium" or "high" please provide additional details:

.....

5. In the light of your knowledge of this GMM and its origination, what is your assessment of its potential to cause harm to human health in the event of exposure?

Negligible	Low	Medium	High

If "medium" or "high" please provide additional details:

.....

6. Does this GMM have the ability to survive, establish and disseminate in the environment?

Yes ☐ No ☑

Form completed by:

Name: DR. SUDHANSHU VRATI

Title: STAFF SCIENTIST

Date: 16TH JUNE 2004

Signature: .....

All details above are correct

ECACC may request further information in order to complete its risk assessment. To whom should such requests be addressed?

Name: DR. G.W. BOTH

Telephone: +61-2-94905169

Fax: +61-2-94905005

E-mail: Gerry.Both@csiro.au

CAMR Today's Research Tomorrow's Health

European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 E-mail: ecacc@camr.org.uk Web site: ecacc.org.uk

Biohazard Risk Assessment

To be completed prior to acceptance of a biological agent into an ECACC repository

For ECACC use only

Type of Deposit: .....

Accession Number: .....

Depositor Code: .....

Activity Class: .....

Signed: ..... Date: .....

For Completion by Depositor

The Biological Agent is:

Animal Cell ☐ Virus ☑ Bacterium ☐ Yeast ☐ Plasmid ☐

Genetically Modified ☑ If yes. What Class:. Category 1

If you have answered Class 2 or above please forward to us any Risk Assessment you have carried out yourselves relating to this deposit.

Other (please define): .....

Species: Replication-defective human adenovirus

Strain: type 5

Identification Code: RAdEs

ACDP Hazard Group[1] 1 ☑ 2 ☐ 3 ☐ 4 ☐ If USA deposit use SALS Category

Does this require a Specified Animal Pathogens Order YES/NO

If yes please refer to the DEFRA Web site for a licence application. www.defra.gov.uk

Brief description of deposit. If the agent is genetically modified include details of inserted gene, method/vehicle for insertion and any expression product.

E1 transcription unit-deleted, replication-defective human Adenovirus (Ad) 5 was modified to contain in its genome, the cDNA encoding Japanese encephalitis virus (JEV) prM and E proteins under the control of the Cytomegalo virus promoter in place of the E1 transcription unit. The recombinant virus RAdEs, thus generated, is unable to replicate in mammalian cells other than HEK293 where Ad5 E1 transcription unit has been integrated permanently. RAdEs is capable of expressing JEV prM and E proteins in mammalian cells.

To be completed if the biological agent is genetically modified

[1] ACDP Advisory Committee on Dangerours Pathogens

Hazard Group 1	A biological agent unlikely to cause human disease.
Hazard Group 2	A biological agent that can cause human disease and may be a hazard to employees, it is unlikely to spread to the community and there is usually effective prohpylaxis and effective treatment available.
Hazard Group 3	A biological agent that can cause severe human disease and presents a serious hazard to employees. It may present a risk of spreading to the community, but there may be a prophylaxix or treatment available.
Hazard Group 4	A biologial agent that causes severe human disease and is a serious hazard to employees. It is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

ecacc
European Collection of Cell Cultures

Health Protection Agency, Porton Down and European Collection of Cell Cultures

This document certifies that

Virus RAdEs

Deposit Reference 04121701

has been accepted as a patent deposit, in accordance with The Budapest Treaty of 1977, with the European Collection of Cell Cultures on 17 December 2004

Dr D H Lewis
General Manager
ECACC